

Entrusted to operate the C.W. Bill Young Cell Transplantation Program, including Be The Match RegistrySM

August 14, 2009

Cdr. Elizabeth Montcalm-Smith Office of Naval Research (ONR 342) 875 N. Randolph St. Arlington, VA 22203-1995

Subject: Quarterly Performance/Technical Report of the National Marrow Donor

Program®

Reference: Grant Award #N00014-08-1-1207 between the Office of Naval Research and the

National Marrow Donor Program

Dear Cdr. Montcalm-Smith:

Enclosed is subject document which provides the performance activity for each statement of work task item of the above reference for the period of April 1, 2009 to June 30, 2009.

Should you have any questions as to the scientific content of the tasks and the performance activity of this progress report, you may contact our Chief Medical Officer – Dennis L Confer, MD directly at 612-362-3425.

With this submittal of the quarterly progress report, the National Marrow Donor Program has satisfied the reporting requirements of the above reference for quarterly documentation. Other such quarterly documentation has been previously submitted under separate cover.

Please direct any questions pertaining to the cooperative agreement to my attention (612-362-3403 or at <u>cabler@nmdp.org</u>).

Sincerely,

Carla Abler-Erickson, MA

Sr. Contracts Representative

Enclosure: Quarterly Report with SF298

Carla Abler Enckson

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Jennifer Ng, PhD – C.W. Bill Young Marrow Donor Recruitment and Research Program,

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NATIONAL MARROW DONOR PROGRAM®

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Grant Award N00014-08-1-1207

QUARTERLY PERFORMANCE / TECHNICAL REPORT FOR APRIL 01, 2009 to JUNE 30, 2009 Period 3

Office of Naval Research

And

The National Marrow Donor Program 3001 Broadway Street N.E.
Minneapolis, MN 55413
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.	eparedness – Objective 1: Recovery of casualties with significant myelosuppression following radiation or
	petimal when care plans are designed and implemented by transplant physicians
IIA.1 Task 1:	Period 3 Activity:
Secure Interest of Transplant Physicians	• During 2009 a total of 103 RITN center staff successfully completed the BRT. Since its creation in 2006 over 1,800 RITN center staff have successfully completed BRT; with a passing rate of 96%.
·	 Held the 2009 RITN conference "Nuclear Terrorism: Hematology/Oncology Center Preparedness" in Bethesda, MD on May 18th (additional details of this conference are listed under AIM II A 2.1).
IIA.1 Task 2:	Period 3 Activity:
GCSF in Radiation Exposure	No activity this period
IIA.1 Task 3:	Period 3 Activity:
Patient Assessment Guidelines and System	STAR Link Web and Do It Yourself (DIY) application efforts were focused on project enhancements and preparation for the Navy Contingency projects including:
Enhancements	Health History Questionnaire (HHQ) enhancements:
	o Void Form feature
	o DIY Form Language changes
	 Completion of the following project initiation and analysis deliverables to support future releases on the Navy Contingency Project:
	 Draft Quality Assurance Plan
	 Draft requirements/use case for iteration 3 (Voids)
	Iteration 4 requirements/use case (Accurint)
	 Define/tag affected donor requirements/use case
	o DIY extension requirements/use case

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- o Communicate to donors requirements/use case
- o Began documenting requirements for managing affected donors /use case
- **Statistic:** DIY Online Donor Registration through <u>www.marrow.org</u> resulted in a **total of 52,252** between 1/1/08 6/30/09.

Data Warehouse/Data Mart Reporting: The NMDP is in the process of creating Data Marts for the purpose of organizational reporting. In the last quarter the DIY Recruitment Data Mart was put into production. This Data Mart will provide the foundation for the Navy Contingency reporting of affected donors.

IIA 1. Task 4:

National Data Collection Model

Period 3 Activity:

• No activity this period

IIA. Contingency Preparedness – Objective 2: Coordination of the care of casualties who will require hematopoietic support will be essential in a contingency situation.

IIA.2 Task 1:

Contingency Response Network

Period 3 Activity:

- Represented the RITN at the Institute of Medicine Workshop: Standards of Care During a Mass Casualty Event held in Chicago, IL on May 8, 2009.
- Conducted the 2009 RITN conference "Nuclear Terrorism: Hematology/Oncology Center Preparedness" in Bethesda, MD on May 18, 2009.
 - o Ninety-two experts in their fields attended this conference.
 - Key note speaker was RADM Anne Kneble (Deputy Director for Preparedness Planning in the Office of the Assistant Secretary for Preparedness and Response, United States Department of Health and Human Services)
 - Morning group sessions included:
 - Threat scenario overview
 - National Disaster Medical System

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Medical response expectations 10, 100, 1000 miles from epicenter Altered standards of medical care overview NMDP planning and data collection o Afternoon interactive breakout workgroups included (each session was held three times so attendees could attend all sessions): Altered standards of care Logistical issues – bed mgmt, use of non-hospital loc, & staffing issues Provision of medical care – early and late care The conference culminated with a report of findings by the afternoon session moderators Represented the RITN at the Radiological/Nuclear Scarce Resource Allocation Workshop conducted by the Assistant Secretary for Preparedness and Response, Department of Health and Human Resources - held in Rockville, MD June 8 - 9, 2009. IIA.2 Task 2: **Period 3 Activity:** Sibling Typing Initiated meeting of a team to evaluate and scope and feasibility of incorporating a related typing **Standard Operating** process into the current NMDP Star system. **Procedures** IIA. Contingency Preparedness – Objective 3: NMDP's critical information technology infrastructure must remain operational during contingency situations that directly affect the Coordinating Center. IIA.3 Task 1: **Period 3 Activity:** I.S. Disaster Additional hardware and software was purchased, installed and configured to support disaster Recovery recovery testing. Additional network segments were also added to support the disaster recovery environment for completing this set of tests. Completed the Disaster Recovery Testing for all Tier 1 applications in April 2009. In addition, the Disaster Recovery Smoke Test for Tier 2 through Tier 4 applications was completed in May 2009 and full Disaster Recovery testing for Tier 2 through 4 applications was successfully completed in

	June 2009.
IIA.3 Task 2:	Period 3 Activity:
Critical Facility and Staff Related	Business Continuity Planning:
Functions	 Continued to assemble NMDP operated donor center readiness kits to prepare these remote NMDP offices to better respond to incidents that impact their operations.
	tion of Matched Donors – Objective 1: Increasing the resolution and quality of the HLA testing of
	stry will speed donor selection.
IIB.1 Task 1:	Period 3 Activity:
Increase Registry Diversity	Cord Blood
	NMDP is conducting research with OB/GYN physicians to understand barriers and motivations to supporting public cord blood donation with their patients. The development phase of the research is now complete, and the fielding of the study will begin this month.
	Adult Donor Registry
	To successfully serve all patients in need of cellular transplantation, the Marketing and Communications Department continues to focus on developing and executing strategies and tactics that help increase the size and diversity of the Be The Match Registry SM by increasing awareness, education and engagement among target audiences.
	During the April – June 2009 time-frame, we developed additional Spanish-language recruitment educational tools to more effectively target the growing Hispanic/Latino community and to motivate them to join the registry. Additionally, we began developing strategies and tactics for the 2009 HBCU program. The program is an integrated marketing approach designed to continue to build upon earlier work in this college segment to engage HBCU students, faculty, alumni and the broader HBCU community in our mission to save lives, specifically by joining the registry. The program will feature audience-specific awareness and educational tools, including a significant social media component to help ensure we reach students where they are today.

	STAR II		
	The STAR II transaction broker was released in May of 2009. Of note was a change to make the HML processor highly configurable with regard to the database versioning for lab typing kits. This will allow the NMDP to more quickly support new and different typing kits on a lab specific basis, and provides much more flexibility in accepting HLA information from labs for recipients and donors. In addition, this change provides flexibility for both operational (patient directed) and research based lab results.		
IIB.1 Task 2:	Period 3 Activity:		
Evaluate HLA- DRB1 High Res typing	• This activity is closed.		
IIB.1 Task 3:	Period 3 Activity:		
Evaluate HLA-C Typing of Donors	This activity is closed.		
IIB.1 Task 4:	Period 3 Activity:		
Evaluate Buccal Swabs	No activity this period.		
IIB 1 Task 5:	Period 3 Activity:		
Enhancing HLA Data for Selected Donors	No activity this period.		
IIB 1 Task 6:	Period 3 Activity:		
Maintain a Quality Control Program	No activity this period.		
_	IIB. Rapid Identification of Matched Donors – Objective 2: Primary DNA typing data can be used within the registry to improve the quality and resolution of volunteer donor HLA assignments.		
IIB 2 Task 1:	Period 3 Activity:		
Collection of Primary Data	No activity this period.		

IIB 2 Task 2:	Period 3 Activity:
Validation of Logic of Primary Data	This activity is closed.
IIB 2 Task 3:	Period 3 Activity:
Reinterpretation of Primary Data	This activity is closed.
IIB 2 Task 4:	Period 3 Activity:
Genotype Lists & Matching Algorithm	 Performed a test re-interpretation of approximately 270,000 probe results to the HLADB 2.40 allele list. Test re-interpretation was successful (by spot validation testing) and data are ready for re- interpretation in production.
_	on of Matched Donors – Objective 3: Registry data on HLA allele and haplotype frequencies and on the can be used to design computer algorithms to predict the best matched donor.
IIB.3 Task 1:	Period 3 Activity:
Phase I of EM Haplotype Logic	• Prototype was further developed for HapLogic Phase III which includes x of 10 matching and sorting, x of 8 matching and sorting, x of 6 matching and sorting, and a single value "allele" sort based on a weighted average matching score. Internal validation testing was begun using this prototype, feedback from this testing will be used to continue developing the prototype next quarter.
	 Internal committee started to discuss key focal areas: 8/8 and 10/10 matching, detailed and multi- race, and a donor readiness score. Committee researched and put together data which would be presented to the NMDP histocompatibility advisory group on July 9, 2009.
IIB 3 Task 2:	Period 3 Activity:
Enhancement of EM	
Algorithm	 An extract of primary DNA data for A, C, B, DRB1, and DQB1 loci reinterpreted to the HLADB 2.24 allele list has been completed. This dataset includes 3.89 million donors typed using DNA methods at recruitment from the 147 detailed race and ethnic combinations that exist in the NMDP donor file.

	• Tools for reducing the genotype lists (which can be on the order of trillions per donor) have been developed. The techniques involve reduction to ARS, a greedy algorithm to restrict allele lists to only alleles required to interpret all genotype lists, and genotype list bootstrapping. The resulting performance improvements were required for practical application of the EM algorithm to generate haplotype frequencies from highly ambiguous typing data.
IIB 3 Task 3: Optimal Registry Size	Period 3 Activity:
Analysis	 Activities completed under IIB 3 Task 2 (above) provided foundational methods and data to support the optimal Registry Size Analysis.
IIB 3 Task 4:	Period 3 Activity:
Target Under- Represented Phenotypes	• ESRI-ARC GIS Geographical Analysis software was used to build a concordance map prototype, normalized over population and recruitment rate. Used a 2-digit, 01:08:03 (common) map, and a 02:44:04 (lower frequency) map. This prototype needs to be developed further in order to confirm that we are able to meet these requirements:
	 Maps would show areas where HLA types are congregated. This would allow targeted recruiting for rare HLA alleles, phenotypes or haplotypes.
	 Maps could be used for patients with rare alleles or haplotypes to identify areas where there may be a related HLA population.
	 Concordant maps could be overlaid for patients with one or two rare haplotypes. Overlap would identify geographic areas where there may be potential donors not yet recruited.
	 Maps would be offered to donors as a way to identify areas where relatives or ancestors may be located or originated, for those interested in such information.
	 Maps could be used to identify trends in HLA population substructure, migration patterns and HLA phylogenetic evolution.
	A database design was created for the underlying database for this aim.

IIB 3 Task 5:	Period 3 Activity:
Bioinformatics Web Site	This activity is closed.
IIB 3 Task 6:	Period 3 Activity:
Consultants to Improve Algorithm	No activity this period.
IIB 3 Task 7:	Period 3 Activity:
Population Genetics	No activity this period.
IIB 3 Task 8:	Period 3 Activity:
Haplotype Matching	No activity this period.
IIB 3 Task 9: Global	Period 3 Activity:
Haplotype/Benchmark	No activity this period.
	ion of Matched Donors – Objective 4: Reducing the time and effort required to identify closely matched gent need of HSC transplants will improve access to transplantation and patient survival in the context of and routine patient care.
IIB.4 Task 1:	Period 3 Activity:
Expand Network Communications	In the last quarter, efforts have been focused on the analysis and realization of request/fulfillment messaging and storage. This foundation (data model & integration) is a prerequisite for implementing improved electronic communication and parallel search stages.
	 Analysis, vetting of request/fulfillment messaging structure through (peer-to-peer) P2P message realization.
	Analysis, vetting of request/fulfillment storage model.
IIB.4 Task 2:	Period 3 Activity:
Central Contingency Management	A research project was developed to validate the 8/8 HLA high resolution match rate predictions for both CAU and AFA patients. This study will validate previous registry benchmark analyses and supply

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	valuable information regarding donor selection in the event of a contingency. During the past quarter:
	 Scientific Services search strategy staff completed donor selections on behalf of the study 'patients' for the initial cohort.
	A contract was established with an HLA testing lab.
	 Beginning next quarter, donors with repository samples will be tested to identify the 8/8 HLA high resolution match rate for the study patients.
IIB.4 Task 3:	Period 3 Activity:
Benchmarking Analysis	This task is closed.
IIB.4 Task 4:	Period 3 Activity:
Expand Capabilities of Collection and	No activity this period.
Apheresis Centers	
important to identify and	tudies – Objective 1: HLA mismatches may differ in their impact on transplant outcome, therefore, it is d quantify the influence of specific HLA mismatches. In contingency situations it will not be possible to perfectly matched donor can be found.
IIC.1 Task 1:	Period 3 Activity:
Donor Recipient Pair Project	In 1994 a retrospective D/R Pair HLA typing project to characterize class I and class II alleles of

donor/recipient paired samples from NMDP's Repository was initiated. The goals of this ongoing research project are to assay the impact of DNA-based HLA matching on unrelated donor transplant outcome, develop strategies for optimal HLA matching, evaluate the impact of matching at alternative HLA loci on transplant outcome and finally to promote the development of DNA-based high resolution HLA typing methodologies.

- Scientific Services staff compiled all outstanding typing issues from prior SGs and distributed samples to a tie-breaker laboratory for final resolution. Completion of all typings was finished in June. Full analysis and audit will be completed early next quarter.
- Sample Group 22 (SG22) period of performance came to a close on April 30, 2009. The contracts

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for SG22 (273 pairs) included intermediate and high resolution HLA typing. During the quarter, the discrepancy, no-make, and linkage analyses were initiated.

• The project period for SG23 began April 30, 2009 and will come to a close on August 31, 2009. The contracts for SG23 (400 pairs) testing includes intermediate and high resolution HLA.

Current HLA matching guidelines for unrelated HCT recommend avoidance of mismatches only within the ARS. This recommendation is based on the hypothesis that amino acid differences outside the ARS are not immunogenic. The ARS allo-reactivity assessment project will give insight into the allowable percent tolerance of matching needed outside of the ARS.

• Initiated investigation of the first class II non-ARS mismatch (DRB1*140101/1454) where both alleles have been seen in the same genotype. Specific queries of the Be The Match Registry allowed for selection of ninety-nine potential donors to be typed at high resolution. Study participation selection will occur in the next quarter once typing results have been completed.

IIC. Immunogenetic Studies – Objective 2: Even when patient and donor are HLA matched, GVHD occurs so other loci may play a role.

IIC 2 Task 1:

Analysis of non-HLA loci

Period 3 Activity:

In 2005 a pilot study to perform high resolution KIR gene typing was launched. The primary objectives of the study were to move technology forward from the current practice of locus level typing to high resolution typing, disseminate information and protocols in an open source mechanism and develop reference lines for use in individual laboratories.

- Resolution continued of 128 potential new KIR alleles found within Phase 1, 2 and 3 of the KIR Typing Pilot. 78 samples were determined to have 46 novel alleles. Only two samples still remain to be typed. Submission, naming and publication should occur within the next two quarters.
- Manuscript preparation for the KIR Typing Pilot Project continued. Further analysis of the data is ongoing. Presentation of the data will occur at the end of next quarter.
- To date 1173 pairs from the Donor/Recipient pair's project have been typed for presence/absence of 14 KIR loci (2DL1-5, 2DS1-5, 3DL1-3 and 3DS1).

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	The IPR database and its applications will allow for storage and analysis of all immunogenetic data collected on NMDP research samples. This database will replace the existing HLA donor/recipient pair's database and facilitate storage and analysis of data from other immunogenetic loci (KIR, microsatellites, single nucleotide polymorphisms, etc).
	 The Scientific Services and Bioinformatics departments continued to collaborate on the design and development of the IPR database application and tools.
	 The application that accepts, validates, and stores incoming HLA and KIR typing data via HML was completed and moved into quality assurance.
	 Business requirements were written for reports which support the business user's ability to track typing requests and their results.
	 Technical specifications were written for an application which loads transplant center typings.
	 Technical specifications were written for an application which compares typings between the labs and the transplant centers.
IIC 2 Task 2:	Period 3 Activity:
Related Pairs Research Repository	No activity this period.
IIC 2 Task 3:	Period 3 Activity:
CIBMTR Integration	No activity this period.

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IID. Clinical Research in Transplantation – Objective 1: Clinical research in transplantation improves transplant outcomes and supports preparedness for a contingency response.

IID.1 Task 1:

Observational Research, Clinical Trials and NIH Transplant Center

Period 3 Activity:

• Staff continued to support trial management activities associated with the 07-Revlimid trial. This included preparing for annual IRB renewal and revising training materials for participating sites.

FormsNet Activity:

- Quality Assurance Testing continues and User Acceptance Testing begins for FormsNet v2.9 (Donor Forms and Functionality). Planned delivery is August 6, 2009.
- Analysis and development continues for FormsNet v2.10 (26 Recipient Forms updates/modifications). Planned delivery is September 9, 2009.
- Analysis and development continues for FormsNet v2.11 (Clinical Trials). Planned delivery is October 2009.

AGNIS Activity:

- Continued support for MD Anderson submission to AGNIS version 1.2, defect fix release completed to correct issues they encountered
- Completed design for AGNIS 2.0, and released supporting documentation
- Updated mandated forms curation to support module based curation (AGNIS 2.0) and ISO 8601 date format
- Refactored AGNIS Service to support Module based curation (AGNIS 2.0)
- Began development for AGNIS 2.0 Publish functionality supporting Forms 2400, 2450, and 2900
- Completed requirements and began development of a tool to assist transplant center data mapping to caDSR curated forms
- Began curation on version 2 of mandated forms
- Support for transplant centers expressing interest in AGNIS development, including University of

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	Minnesota, Roswell Park, City of Hope, and Karmanos Cancer Institute.
IID.1 Task 2: Research with NMDP Donors	 Period 3 Activity: Staff explored options on supporting a research study requesting research samples for unrelated donors.
IID.1 Task 3:	Period 3 Activity:
Expand Immuno- biology Research	No activity this period.

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ACRONYM LIST

AABB	American Association of Blood Banks	IND	Investigational New Drug
AC	Apheresis Center	ICRHER	International Consortium for Research on Health
			Effects of Radiation
AFA	African American	IS	Information Services
AGNIS	A Growable Network Information System	IT	Information Technology
AML	Acute Myelogenous Leukemia	IRB	Institutional Review Board
API	Asian Pacific Islander	JCHO	Joint Commission
			of Healthcare Organizations
ARS	Acute Radiation Syndrome (also known as Acute	KIR	Killer Immunoglobulin-like Receptor
	Radiation Sickness)		
ASBMT	American Society for Blood and Marrow	LSSG	Life Sciences Strategy Group
	Transplantation		
ASHI	American Society for Histocompatibility and	MHC	Major Histocompatibility Complex
	Immunogenetics		
B-LCLs	B-Lymphocytic Cell Lines	MICA	MHC Class I-Like Molecule, Chain A
BARDA	Biomedical Advanced Research and	MICB	MHC Class I-Like Molecule, Chain B
	Development Authority		
BMT CTN	Blood and Marrow Transplant - Clinical Trials	MDACC	MD Anderson Cancer Center
	Network		
BRT	Basic Radiation Training	MSKCC	Memorial Sloan-Kettering Cancer Center
CAU	Caucasian	MUD	Matched Unrelated Donor
C&A	Certification and Accreditation	NAM	Native American
CBMTG	Canadian Blood and Marrow Transplant Group	NCBM	National Conference of Black Mayors
CBB	Cord Blood Bank	NCI	National Cancer Institute
CBC	Congressional Black Caucus	NEMO	
CBS	Canadian Blood Service	NHLBI	National Heart Lung and Blood Institute
CBU	Cord Blood Unit	NIH	National Institutes of Health
CC	Collection Center	NIMS	National Incident Management System
CHTC	Certified Hematopoeitic Transplant Coordinator	NK	Natural Killer
CIBMTR	Center for International Blood & Marrow	NMDP	National Marrow Donor Program

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	Transplant Research		
CLIA	Clinical Laboratory Improvement Amendment	NRP	National Response Plan
CME	Continuing Medical Education	NST	Non-myeloablative Allogeneic Stem Cell
			Transplantation
CMF	Community Matching Funds	OCR/ICR	Optical Character Recognition/Intelligent Character
			Recognition
COG	Children's Oncology Group	OIT	Office of Information Technology
CREG	Cross Reactive Groups	OMB	Office of Management and Budget
CSS	Center Support Services	ONR	Office of Naval Research
CT	Confirmatory Testing	P2P	Peer-to-Peer
CTA	Clinical Trial Application	PBMC	Peripheral Blood Mononuclear Cells
DC	Donor Center	PBSC	Peripheral Blood Stem Cell
DIY	Do it yourself	PCR	Polymerase Chain Reaction
DKMS	Deutsche Knochenmarkspenderdatei	PI	Principle Investigator
DMSO	Dimethylsulphoxide	POI	Procedures of Interaction
DNA	Deoxyribonucleic Acid	PSA	Public Service Announcement
D/R	Donor/Recipient	QC	Quality control
DSMB	Data Safety Monitoring Board	RCC	Renal Cell Carcinoma
EBMT	European Group for Blood and Marrow	RCI BMT	Resource for Clinical Investigations in Blood and
	Transplantation		Marrow Transplantation
EM	Expectation Maximization	REAC/TS	Radiation Emergency Assistance Center/Training Site
EMDIS	European Marrow Donor Information System	RFP	Request for Proposal
ERSI	Environment Remote Sensing Institute	RFQ	Request for Quotation
FBI	Federal Bureau of Investigation	RG	Recruitment Group
FDA	Food and Drug Administration	RITN	Radiation Injury Treatment Network
FDR	Fund Drive Request	SBT	Sequence Based Typing
Fst	Fixation Index	SCTOD	Stem Cell Therapeutics Outcome Database
GETS	Government Emergency Telecommunications	SG	Sample Group
	Service		
GCSF	Granulocyte-Colony Stimulating Factor (also	SLW	STAR Link® Web
	known as filgrastim)		

QUARTER PROGRESS REPORT

GIS	Geographic Information System	SSA	Search Strategy Advice
GVHD	Graft vs Host Disease	SSO	Sequence Specific Oligonucleotides
HBCU	Historical Black Colleges and University	SSP	Sequence Specific Primers
HCT	Hematopoietic Cell Transplantation	SSOP	Sequence Specific Oligonucleotide Probes
HHQ	Health History Questionnaire	SSRS	Sample Storage Research Study
HHS	Health and Human Services	STAR [®]	Search, Tracking and Registry
HIPAA	Health Insurance Portability and Accountability	TC	Transplant Center
	Act		
HIV	Human Immunodeficiency Virus	TED	Transplant Essential Data
HLA	Human Leukocyte Antigen	TNC	Total Nucleated Cell
HML	Histoimmunogenetics Mark-up Language	TSA	Transportation Security Agency
HR	High Resolution	TTY	Text Telephone
HRSA	Health Resources and Services Administration	UI	User Interface
HSC	Hematopoietic Stem Cell	URD	Unrelated Donor
IBWC	Immunobiology Working Committee	WGA	Whole Genome Amplification
IDM	Infectious Disease Markers	WMDA	World Marrow Donor Association
IHWG	International Histocompatibility Working Group	WU	Work-up
IPR	Immunobiology Project Results		